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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/761,837 | 01/20/2004 | Stanley Johnston | JOHNSTON03-01 | 4082 |

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| EXAMINER |
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HUI, SAN MING R

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| ART UNIT | PAPER NUMBER |
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1617

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| MAIL DATE | DELIVERY MODE |
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01/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/761,837 | JOHNSTON, STANLEY | |
| | Examiner | Art Unit | |
| | San-ming Hui | 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,7,9,12,15 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7,9,12,15 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendments filed June 3, 2008 have been entered.

Claims 1, 3, 5, 7, 9, 12, 15, and 18-21 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5, 7, 9, 12, 15, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mooney et al. (US 5,814,031), WO97/04764 ('764), Crawford (US 5,973,010), Merck (Merck Index, 11th ed., monograph 4778, page 7769-770, 1989), Burks (Phys. Ther. 1998;78:212-218), and US2003/0068331 ('331).

Mooney et al. teaches hydrocortisone, bacitracin, and polymixin B as useful in wound care composition as antimicrobial and anti-inflammatory agents (See claims 13 and 26).

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'764 teaches 0.025 to 50% of phenylephrine HCl as useful in wound treatment to reduce bleeding (See the abstract, page 2, line 25).

Crawford teaches ichthammol as useful in wound treatment composition (see the abstract for example).

Merck teaches 8-hydroxyquinoline as useful as disinfectant.

Burks teaches 10% povidone-iodine solution as useful as topical antiseptics in wound treatment (See page 212, first two paragraphs).

Finally, '331 teaches the use of benzoin that will aid the wound treatment as it can form a coating over a cutaneous wounds (See paragraph [0009]).

The references do not expressly teach the agents to be put together in a single composition. The references do not expressly teach the weight percentage of the agents herein claimed. The references do not teach the herein claimed method of making such composition.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate all the herein claimed agents together, in the weight ratio herein claimed, into a single composition. It would have been obvious to one of ordinary skill in the art at the time of invention to make such wound treating composition by combining the herein claimed active together.

One of ordinary skill in the art would have been motivated to incorporate all the herein claimed agents together, in the weight ratio herein claimed, into a single composition. Combining one or more agents, which are known to be useful to treat wound or aiding in wound healing individually, into a single composition useful for the

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very same purpose is prima facie obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)). Furthermore, the optimization of result effect parameters (dosage range, dosing regimens) is obvious as being within the skill of the artisan. One of ordinary skill in the art would have been motivated to make such wound treating composition by combining the herein claimed active together. Simply mixing or combining the herein claimed agents together to form the herein claimed composition is considered obvious as being within the purview of skilled artisan.

Response to Arguments

Applicant's arguments filed June 3, 2008 averring the cited prior art's failure to provide motivation to combine the herein claimed ingredients into a single composition have been fully considered but they are not persuasive. The basis of the instant rejection resides on the fact that the herein claimed agents are individually known to be useful to treat wound. Combining them together in a single composition useful for the very same purpose - treating wound, would be obvious (See *Kerkhoven supra*).

Applicant's arguments filed June 3, 2008 averring the cited prior art's failure to suggest the stability of the instant invention have been considered, but are not found persuasive. It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548

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(CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The examiner notes that there is no data to evaluate the stability of the instant composition. Absent evidence showing the criticality of the instant combination, possessing the teachings of the cited prior art, one of ordinary skill in the art would be motivated to combine the herein claimed compounds into a single composition useful for treating wounds.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617

/San-ming Hui/
Primary Examiner, Art Unit 1617